

REMARKS

Claims 34-45 are pending and considered.

Provisional Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejected claims 33, 38, and 42 under the judicially created doctrine of obviousness-type double patenting in view of certain claims of co-pending U.S. Application No. 09/911,903. December Action at page 3. Because this is a provisional rejection, it is premature to address it at this time until the claims in this case are otherwise considered allowable. At that time, the claims in this case and the claims in the other case can be evaluated to determine the propriety of the rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 34 to 45 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. (December Action at page 4). Specifically, the Examiner stated that the specification enables methods "via the disclosed Envelope Caller..." but "does not reasonably provide enablement for the analysis of the signal 'to determine if the signal meets a threshold test of an allele caller making a correct call' by all other means" *Id.* Applicants respectfully traverse the rejection.

To maintain an enablement rejection, the Examiner bears the burden of establishing that one skilled in the art would require undue experimentation to practice the claimed invention. The Examiner previously had listed eight factors from *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988), that may be considered for an undue experimentation analysis. (Paper No. 20 at page 3.) In the December Action, the Examiner first focuses on the breadth of the claims and the guidance in the specification

concerning the Envelope Caller example (December Action at page 5, second paragraph, through the first full sentence of page 6).

The Examiner then states that "for one of skill in the art to analyze the signal to determine if the signal meets a threshold test of an allele caller making a correct call; one would be required to derive specific criteria(s)/parameter(s) and operations(s)/functions(s) suitable to determine if the signal meets a threshold test of an allele caller to make a correct call." December Action at page 6. The Examiner states that in the present case "for such a derivation to occur one of skill in the art would be required to make independent decisions and [judgments] regarding: 1) the derivation of the initial governing parameters for a threshold test; 2) ascertain that the threshold test indicates a correct call for an allele caller through testing and validation; 3) derive procedures for the analysis of the signal in order to determine if the signal meets the threshold test of an allele caller to make a correct call." *Id.*

The Examiner concludes that "[s]uch independent decisions, judgments, tests, and validation are not considered to be routine experimentation and utilize inventive skill to develop other means for 'analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call' (as broadly encompassed by the instant claims)." *Id.* The Examiner further states that the specification discloses no other methods "for 'analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call'" and that no other methods "appear to have been known in the art." *Id.* at pages 6 to 7.

Applicants assert that the Examiner has not established nonenablement under § 112, first paragraph. The fact that a claim is broad and a specification explicitly

describes one embodiment, does not necessarily require a conclusion that the specification fails to enable other embodiments encompassed by the claim. Section 112, first paragraph, does not foreclose any experimentation. Rather, it does not permit undue experimentation. Also, contrary to the Examiner's assertions, a finding of undue experimentation is not required even if independent decisions, judgments, tests, and validation are carried out by one skilled in the art to practice other methods encompassed by the claims.

For example, a claim may be directed to a method with a step that provides a novel solution that had never been considered before. There may be many different ways to accomplish the solution that were not in the prior art, because no one had considered the solution before. Also, without undue experimentation, using their experience in the field, those skilled in the art may design many different ways to accomplish the solution even if the specification explicitly teaches only one way. MPEP 2164.02 states "[t]he specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 U.S.P.Q. 642, 645 (CCPA 1970)."

That is precisely the situation here. The level of skill in the art is quite high here. In fact, Hugh Pasika has informed the undersigned that for years leading up to the filing date of this patent application, researchers had performed allele calling manually and thus, such researchers had developed a high degree of cognitive skill in differentiating allele signatures from spurious peaks, as well as distinguishing difficult allele-calling data. That skill could have been applied to determine other ways to perform a threshold

test according to the claimed invention without undue experimentation. Here, the Examiner has failed to present any evidence supporting a position that undue experimentation would have been required by one skilled in the art to practice other threshold tests.

Accordingly, applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph, rejection.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 34, 38, and 42 under 35 U.S.C. § 102(b) as allegedly being anticipated by Palsson et al., *Using Quality Measure to Facilitate Allele Calling in High-Throughput Genotyping*, Genome Research, Vol. 9, pp. 1002-12 ("Palsson"). (December Action at page 6).

Applicants respectfully submit that claims 34, 38, and 42 are not anticipated by Palsson. Independent claims 34, 38, and 42 recite, *inter alia*, "analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call" or "analyze the signal to determine if the signal meets a threshold test of an allele caller making a correct call." Those claims further recite, *inter alia*, "making an allele call for the signal if the threshold test is met" or "make an allele call for the signal if the threshold test is met."

Palsson fails to perform any threshold test when making an allele call. Instead, Palsson discusses taking already-made allele calls of an caller program (Decode-GT) and filters them according to heuristic criteria to classify them as good, bad, or ambiguous calls (Palsson, at 1003-1005). Thus, Palsson discusses processing already-

made allele calls rather than using a threshold test to analyze data and determine if an allele call should be made.

In fact, the Examiner's summary of Palsson is consistent with that distinction. Specifically, the Examiner stated that "[a]llege calls are made for the signal if the threshold is [met] (represented as the accepted good calls), whereas allele calls that do not meet the threshold (categorized as bad calls) are discarded" December Action at page 8. Thus, as summarized by the Examiner, Palsson discusses classifying and discarding allele calls **that have already been made**. Palsson fails to disclose analyzing a signal to determine if the signal meets a threshold test and making an allele call only if the threshold test is met.

Accordingly, the Examiner failed to establish that Palsson discloses at least the above elements of claims 34, 38, and 42. Thus, applicants respectfully request reconsideration and withdrawal of the § 102(b) rejection in view of Palsson.

Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected claims 34 to 45 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,807,490 to Perlin ("Perlin"). (December Action at page 8). The Examiner contends that

Perlin discloses a process for analyzing nucleic acid samples that produce quantitative data, and then analyzes this data to characterize a DNA fragment (allele calling) to reduce sizing and quantitation errors in fragment analysis. Signals representing nucleic acid information from DNA sequencers are acquired/received and stored in a file. The signal information is then analyzed and allele calls are made wherein: 1) the largest peak (area or height) is found; 2) all peaks from the signal that either (a) have a DNA length that is not in a window of the allelic ladder, or (b) have a DNA [amount] that is not within some minimum percentage of the largest peak are removed; 3) calling the alleles by matching the DNA lengths of each sample peak to the DNA sizing windows and the allelic ladder; 4) applying rules to check for possible data artifacts; 5)

computation of a quality score; and 6) recording the designated alleles and the quality of the result.

Id. at pages 8 to 9 (citations omitted).

The Examiner then contends that Figure 4 "depicts the signal representing nucleic acid information is used to determine nucleic acid length, the signal information has 'at least three panels' for making an allele call (the signal is bounded by deep local minima), and the signal energy level (claim 35; and refer to below definition in the specification)."

Id. at page 9. Finally, the Examiner contends that "[t]he inventor further discloses features of a system and software (computer readable medium) for the above described method." *Id.* (citations omitted).

Applicants respectfully submit that claims 34 to 45 are not anticipated by Perlin. Independent claims 34, 38, and 42 recite, *inter alia*, "analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call" or "analyze the signal to determine if the signal meets a threshold test of an allele caller making a correct call." These claims further recite, *inter alia*, "making an allele call for the signal if the threshold test is met" or "make an allele call for the signal if the threshold test is met."

Perlin fails to "analyze the signal to determine if the signal meets a threshold test of an allele caller making a correct call" and "make an allele call for the signal if the threshold test is met." Rather, as indicated at column 24, starting at line 38, Perlin filters out certain peaks, but always makes an allele call. In other words, Perlin's filtering fails to show the use of a threshold test to determine if an allele call is made. In applicants' claimed method, an allele call is made **if the threshold test is met**. In Perlin's method, an allele call is always made.

Thus, for at least that reason, Perlin fails to anticipate independent claims 34, 38, and 42. Claims 35 to 37, 39 to 41, and 43 to 45 all ultimately depend from one of those three independent claims. Thus, for at least the same reason, Perlin fails to anticipate those dependent claims. Accordingly, applicants need not address the Examiner's additional contentions concerning additional elements in any of the claims. The decision not to address certain of those additional contentions is not acquiescence to the contentions.

The Examiner's contention concerning Figure 4 of Perlin, however, is not understood. Figure 4 of Perlin does not appear to teach use of nucleic acid information to determine at least panel determination as claimed in dependent claims 35 to 37, 39 to 41, and 43 to 45. Thus, the Examiner has not established that Perlin anticipates those dependent claims for at least this additional reason.

Applicants respectfully request reconsideration and withdrawal of the § 102(e) rejection in view of Perlin.

CONCLUSION

Applicants request the Examiner's reconsideration and reexamination of the application, and the timely allowance of the application.

If the Examiner does not agree that the application is in condition for allowance, Applicants request the Examiner to call the undersigned at 650-849-6620 to schedule an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 17, 2005

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